Blood Glucose Test Strips Package Insert

REF DTG-GL5PLUS	English

PRINCIPLE AND INTENDED USE

The Clarity Plus Blood Glucose Test Strips are thin strips with a chemical reagent system. They work with the Clarity Plus Blood Glucose Meter to measure the glucose concentration in whole blood. Blood is applied to the end tip of the test strip. The blood is then automatically absorbed into the reaction cell. The reaction takes place in the reaction cell. A transient electrical current is formed during the reaction which is detected by the meter. The blood glucose concentration is then calculated based on the electrical current. The result is then shown on the meter display. The Clarity Plus meters are calibrated to display plasma equivalent results.

For *in vitro* diagnostic use. Test strips are only to be used outside the body for testing purposes. For the quantitative measurement of glucose in capillary whole blood from the finger, forearm and palm, by people with diabetes at home and by healthcare professionals as an aid in monitoring the effectiveness of diabetes control programs.

COMPOSITION

Each Clarity Plus test strip contains the following reactive chemicals: Glucose oxidase (from *Aspergillus niger*) < 25 IU, Mediator < 300 µg, Buffer < 500 µg, Non-reactive Ingredient < 1 mg.

Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Test strips should be stored in their protective vial. The vial's cap must be tightly closed. This is to keep the test strips in good working condition.
- Store test strips in a cool, dry place at room temperature, 15-30°C (59-86°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This is to ensure accurate results.
- Do not store the test strips outside of their protective vial. Test strips must be stored in their original vial. The cap must be tightly closed.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap immediately after removing a test strip.
- Use the test strip immediately after removing it from the vial.
- Do not use your test strips past the unopened expiration date. The expiration date is printed on the vial. Using test strips past the expiration date may produce incorrect test results.

  Note: All expiration dates are printed in Year-Month format. 2010-01 means January 2010.
- A new vial of test strips may be used for 3 months after first being opened. The opened vial expiration date is 3 months after the date the vial was first opened. Write the opened vial expiration date on the vial label after opening.

PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are to be used only outside the body. The test strips are to be used only for testing purposes.
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give incorrect blood glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Only apply the sample to the tip of the test strip. Do not apply blood or control solution to the top of the test strip. This may result in an inaccurate reading.
- Check the code chip before running a blood glucose test. Make sure to use the code chip that is contained with that vial of strips. Insert the code chip into the code chip slot. The code chip slot is located on the right side of the meter.
- Discard the vial and any unused test strips 3 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This damage can cause incorrect readings.
- Keep the test strip vial away from children and animals.
- Consult your healthcare professional before making any changes in your treatment plan.

MATERIALS PROVIDED

- Test Strips
- Code Chip
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

INSTRUCTIONS FOR USE

See your User's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial. Remove a test strip for testing. Replace the cap immediately. This is to protect the remaining test strips from moisture in the air.
2. Run the blood glucose test following the User Manual's instructions.
3. The blood glucose test result will be shown on the meter display window. This result should fall within the target range. Your healthcare professional should recommend your target range. If your blood glucose test results are higher or lower, ask your healthcare professional what to do. Always consult your healthcare professional before making any changes to your treatment plan.

IMPORTANT: Clarity Plus Blood Glucose Monitoring System allows alternative site testing for forearm and palm testing in additional to fingertip testing. There are important differences between forearm, palm and fingertip samples that you should know. Important information about forearm and palm glucose testing:

- When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a healthcare professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes:[1]

Time	Range (mg/dL)	Range (mmol/L)
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Handle your blood glucose meter carefully. See your User's Manual for detailed instructions for meter care. The quality control test should be used to check that the meter and test strips are working together properly. Follow the test procedure in your User's Manual to run a quality control test. Two ranges CTRL Low and CTRL High are shown on the test strip vial label. Contact Clarity Diagnostics Customer/Technical support at 1-877-485-7877 for information on purchasing the control solution.

For confirmation of results, Low Control tests should fall within the CTRL Low range, and High Control tests should fall within the CTRL High range. When testing with Low Control, make sure you are matching the results to the CTRL Low range on the vial label.

CAUTION: If your quality control test result falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood. This may be a sign that the system is not working properly. If you cannot correct the problem, contact Clarity Diagnostics Technical Support for help.

LIMITATIONS

- The Clarity Plus meter, test strips and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- Use only with whole blood. Do not use with serum or plasma samples.
- Do not use for testing newborns.
- Do not use the meter in any manner not specified by Clarity Diagnostics. Otherwise, the protection provided by the meter may be impaired.
- Very high (above 55%) and very low (below 30%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- Abnormally high levels of vitamin C, Acetaminophen, Uric Acid, L-Dopa, Tolazamide or other reducing substances will produce false high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 1.1-33.3 mmol/L (20 to 600 mg/dL).
- Fatty substances (triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL) have no major effect on blood glucose test results.
- The Clarity Plus Blood Glucose Monitoring System has shown to be properly working at properly in studies at altitudes up to 8,516ft (2,595 meters).
- Severely ill persons should not run the glucose test with the Clarity Plus Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with Clarity Plus Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions when disposing of materials.

PERFORMANCE CHARACTERISTICS

Reproducibility, Precision

Ten replicate assays were each run on ten Clarity Plus Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results provided the following estimates for reproducibility, precision.

MEAN	46 mg/dL	79 mg/dL	149 mg/dL	244 mg/dL	380 mg/dL
Standard Deviation (mg/dL) or Coefficient of Variation (CV)	2.5 mg/dL	3.3%	3.0%	3.1%	2.4%

Intermediate Precision

Ten replicate assays drawn from three strip lots were run on ten Clarity Plus Blood Glucose Meters. These tests were run each day for a total of ten days. Control solutions at three concentration levels were used in the testing. The results provided the following intermediate precision estimates.

#	MEAN	Standard Deviation (mg/dL) or Coefficient of Variation (CV)
Strip Lot 1	43 mg/dL	1.9 mg/dL
	136 mg/dL	3.7% (CV)
	363 mg/dL	3.3% (CV)
Strip Lot 2	37 mg/dL	2.2 mg/dL
	129 mg/dL	3.7% (CV)
	349 mg/dL	3.8% (CV)
Strip Lot 3	39 mg/dL	1.9 mg/dL
	131 mg/dL	4.3% (CV)
	370 mg/dL	2.8% (CV)

System Accuracy

The capillary blood glucose measurements from 107 participants were taken by a trained technician using the Clarity Plus Blood Glucose Meter (y). Capillary blood samples were obtained from fingertip, palm and forearm sampling sites for the Clarity Plus Blood Glucose Meter testing. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results: Clarity Plus (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept	R	N
Fingertip	0.9972	-4.6130	0.9924	244
Palm	0.9702	2.8354	0..9821	214
Forearm	0.9419	5.5952	0.9778	214

Fingertip samples were used for YSI reference measurement.

The sample range was 43 to 473 mg/dL for Clarity Plus Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 47 to 399 mg/dL for Clarity Plus Blood Glucose Meter testing with blood sampled from palm and forearm sites.

Fingertip Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
97/208 (46.6%)	159/208 (76.4%)	194/208 (93.3%)	208/208 (100%)
Fingertip Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
11/36 (30.6%)	29/36 (80.6%)	36/36 (100%)	

Palm Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
88/198 (44.4%)	144/198 (72.7%)	187/198 (94.4%)	197/198 (99.5%)
Palm Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
10/16 (62.5%)	16/16 (100.0%)	16/16 (100.0%)	

Forearm Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
73/198 (36.9%)	131/198 (66.2%)	172/198 (86.9%)	197/198 (99.5%)
Forearm Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
14/16 (87.5%)	16/16 (100.0%)	16/16 (100.0%)	

Consumer Study

A consumer study was performed by testing three test strip lots. Participants and a trained technician used the Clarity Plus Blood Glucose Monitoring System. This study showed that the patient can run the test as accurately as the trained technician.

Clarity Plus tests: Linear regression of Participant (y) versus YSI Reference value and Linear regression of Technician (y) versus YSI Reference value					
Strip Lot	Tested By	Slope	Intercept	R	N
Lot 1	Layperson	0.9881	-2.3697	0.9862	214
Lot 1	Technician	0.9927	-3.6585	0.9857	214
Lot 2	Layperson	0.9355	4.5351	0.9867	214
Lot 2	Technician	0.9457	2.6854	0.9851	214
Lot 3	Layperson	0.9700	5.9324	0.9827	214
Lot 3	Technician	0.9931	4.1391	0.9843	214

Please refer to your meter's User's Manual for complete instructions. For help with any additional questions or issues, please contact Clarity Diagnostics Technical /Customer Support at 1-877-485-787.

REFERENCES

1. ADA Clinical Practice Recommendations, 2003.

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Printed in China

Number: 1150489602
Effective Date: 2014-xx-xx